UNITED STATES DISTRICT COURT DISTRICT OF NEW JERSEY

HELSINN HEALTHCARE S.A., et al., : CIVIL ACTION NO. 11-3962 (MLC)

Plaintiffs,

v.

DR. REDDY'S LABORATORIES LTD., et al.,

Defendants.

OUTLINE OF SUPPLEMENTAL OPINION

PKE	LLIMIIN	IARY S	STATEMENT	_			
I.	Find	Findings of Fact					
	A.	Med	Medical treatment for emesis				
	B.	The	patents-in-suit				
	C.	Factual chronology					
		1.	Syntex and the genus '333 patent	12			
		2.	Roche Syntex further development process	16			
		3.	Helsinn license from Roche	23			
		4.	The Oread agreements	30			
		5.	FDA meeting March 10, 1999	33			
		6.	Phase III protocol	40			
		7.	Commencement of Phase III trials	49			
		8.	The SP agreements	51			
		9.	The MGI agreements	55			
		10.	Status of Phase III clinical trials on January 30, 2002	62			
		11.	Status as of patent application date, January 30, 2003	73			
		12.	Issuance of patents-in-suit	78			
		13.	Claim construction rulings regarding prosecution history	79			
		14.	ANDA filings by Teva and others	81			

II.	Conclusions of Law					82
	A.	On-sale bar				82
		1.	Lega	Legal standards and post-AIA statutory construction		
			a.	Historica	l analysis	83
			b.	Parties' a	arguments regarding on-sale bar	86
			c.	Interpret	ing the legal standard	87
				1. St	atutory construction	87
				2. A	gency guidelines	89
				3. Le	egislative history	90
				4. Pu	ablic policy considerations	91
			d.	Applicati	on of legal standards	92
				1. St	atutory construction	92
				2. A	gency guidelines	95
				3. Le	egislative history	96
				4. Pu	ablic policy considerations	98
		2.	Find	ings as to s	ale or offer to sell pre-AIA	100
			a.	Applicab	le legal standards	101
			b.	Parties' a	rguments	104
			c.	Analysis		106
		3.	Find	ings as to s	ale or offer to sell post-AIA	109
			a.	Legal sta	ndard	109
			b.	Parties' a	rguments	112
			c.	Analysis		115
		4.	dy for patenting	117		
			a.	Legal sta	ndards	117
			b.	Applied	legal standards	121
				1. Pa	arties' arguments	122
				2. Ex	xpert opinions	123
				3. A	nalysis	141
		5.	Con	clusions as	to on-sale bar claims	146
	B.	Written Description				146
			1.	Legal sta	ndards	146
			2.	Findings	and conclusions on written description	147
	C.	Infringement				
		1.	1. Legal standards			
		2.	Find	ings and co	nclusions on infringement	154
			a.	Parties' a	arguments	154

		b. Analysis	158
D.	Defi	161	
	1.	Expert testimony	162
	2.	Analysis	163
CONCLUS	165		